

DETAILED ACTION

This office action is in response to the reply 1/20/2011

Currently claims 1-21 are pending examination.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non-provisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/385, 571, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Claim 16 does not find support in the provisional application 60/385,571 and as such will be granted a priority date of 6/5/2003.

Declaration

The declaration of Anuj Chauhan filed 12/20/2010 is acknowledged and has been considered. Examiner would like to note that the declaration should be titled "Declaration under 37 C.F.R. 1.131" and not "Declaration under 37 C.F.R 1.132."

Regarding the declaration submitted, Examiner would like to acknowledge that Attachments A and B do seem to establish conception of the claimed invention. However,

Applicant hasn't firmly established reduction to practice. Evidence has been provided demonstrating that conception of the invention occurred prior to Resnick, however more evidence of reduction to practice is required. While applicant has demonstrated that reduction to practice was present in October 2001, the actual date of reduction was not provided and therefore, it is unclear if diligence is required. It is noted that if reduction to practice occurred prior to Resnick, applicant simply needs to swear to that fact. However, if reduction to practice occurred after Resnick, the exact date when reduction to practice occurred must be provided. Regarding diligence, if the reduction to practice occurred before 3/29/2001, no diligence is necessary; however, if reduction occurred after 3/29/2001, applicants are required to demonstrate diligence from the time period prior to 3/29/2001 until the actual reduction to practice.

It is also noted that the applicant must make the affidavit. If several individuals comprise the applicant, the affidavit should be executed by each of those individuals. In the event that the applicant is deceased, hostile or otherwise unavailable, a showing of such unavailability should include a statement of the steps taken to obtain an affidavit or to locate the individual. The affidavit provided was made only by Anuj Chauhan.

Maintained/Modified Rejections

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 4-5, 7-15 and 20 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Resnick (US 2002/0141760), Ding (PSTT, Vol. 1, No. 8, Nov 1998), Vandamme (Progress in Retinal and Eye Research 21 (2002)15-34), Nagarsenker et al (Int. Journal of Pharmaceutics 190 (1999) 63-71) and Paul et al (Current Science, Vol. 80, No. 8, 25 April 2001). Rejection modification necessitated by claim amendment.

Regarding claims 1, 4, 9 and 12: Resnick teaches a contact lens containing nanospheres that are incorporated directly therein (paragraphs 0003 and 0006). Resnick further teaches methods of incorporating drugs and therapeutic agents into the contact lens for the purpose of drug delivery to the eye (paragraph 0019 and claim 2) as well as a kit (title; fig. 3). Resnick refers to US patents 5,891,932 and 4,865,439 in paragraph 0006 for their teaching

of typical contact lenses that Resnick uses as starting materials. Said patents teach soft contact lenses and incorporation of 2-hydroxyethylmethacrylate as well as storing the lenses in saline solution.

Resnick is silent to the phrase "optically transparent", however the definition of said term in applicant's specification states, "a degree of transparency equivalent to that of p-HEMA or other material employed as a contact lens". The materials taught in Resnick read on said definition.

Ding is cited to demonstrate that it's well known in the art that nanoparticles can be utilized, which provide sustained drug release and prolonged therapeutic activity for the delivery of either hydrophobic or hydrophilic ophthalmic drugs (Pg 332-333). Furthermore controlled particle size and control of the rate of the drug release must be further examined.

Regarding claims 10-11 and 14-15: Resnick is silent to the particulars of the kit claimed in the instant claims.

It is well within the knowledge of one of ordinary skill in the art to include a kit or article of manufacture because they provide a convenient mechanism to disperse products to consumers. Additionally, labels containing indications, directions, warnings, etc. are mandated. A practitioner would reasonably expect a kit comprising the drug delivery system of Resnick to provide a convenient mechanism to disperse the product to consumers as well as inform the consumer of indications, directions, and so on. Therefore, in Resnick it would have been obvious to one of ordinary skill in the art to package and label delivery system in a kit or article of manufacture.

It is also well within the knowledge of one of ordinary skill in the art to include a drug-saturated solution in the kit so the drug does not diffuse out of the contact lens and become diluted. A practitioner would reasonably expect the contact lens to have a therapeutically effective amount or concentration of drug. Therefore, in Resnick it would have also been

obvious to one of ordinary skill in the art to include a drug-saturated solution in a kit or article of manufacture.

Resnick fails to teach the ophthalmic drug nanoparticles to be encapsulated with an encapsulation material selected dependent on the drug characteristic (hydrophobic or hydrophilic), such as liposomes or micro emulsions as recited by instant claims 1, 5 and 8 and the ophthalmic drug being pilocarpine, as recited by instant claim 20.

Vandamme teaches micro emulsions as ocular drug delivery systems, which are thermodynamically stable and inherently provide the capacity to make soluble lipophilic drugs (Pg. 16). The main advantage of the micro-emulsion is the increase in the solubilization of drugs. Table 4 demonstrates a microemulsion containing the drug pilocarpine. Paul further teaches that micro-emulsions allow sustained release or controlled drug release for ocular administration (Pg 995).

Nagarsenker teaches the preparation and evaluation of liposomal formulations for ocular delivery, which can serve as a slow release depot. Ophthalmic drugs were entrapped in liposomes. Liposomes have the ability to entrap hydrophilic compounds in the aqueous compartment and to incorporate hydrophobic molecules in the lipid bilayers (Pg 64).

Both Vandamme and Nagarsenker teach encapsulation materials, liposomes and micro emulsions that can be used with hydrophilic or lipophilic (which are hydrophobic).

It would have been prima facie obvious to one of skill in the art at the time the invention was made to combine to teaching of Resnick/Vandamme and Nagarsenker to arrive at the instant invention. One of skill in the art would have been motivated to select one of the encapsulations materials, micro encapsulation or liposomes as taught by Vandamme and Nagarsenker depending on the drug utilized in the nanoparticles, hydrophobic or hydrophilic, as Vandamme teaches that micro emulsions make lipophilic drugs more soluble and liposomes are efficient for slow release depot of drugs. Finally one of skill in the art would expect

reasonable success because Resnick/Vandamme/Nagarsenker all teach controlled release ocular drug delivery.

6. Claims 6 and 17-19 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Resnick (US 2002/0141760), Ding (PSTT, Vol. 1, No. 8, Nov 1998), Vandamme (Progress in Retinal and Eye Research 21 (2002)15-34), Nagarsenker et al (Int. Journal of Pharmaceutics 190 (1999) 63-71) and Paul et al (Current Science, Vol. 80, No. 8, 25 April 2001) as applied to claims 1, 4-5, 7-15 and 20 above, and further in view of Darougar et al (US 6,264,971).

Resnick/Vandamme/Nagarsenker teach the elements of claim 1, but are silent to the particular ophthalmic drugs recited in claims 6 and 17-19.

Darougar teaches an ocular insert that release an ophthalmic drug in a controlled, sustained fashion (abstract). Said ophthalmic drugs include antibiotics such as gentamycin, anti-microbial drugs, anti-inflammatories such as prednisolone acetate, non-steroidal agents such as diclofenac (i.e., Voltaren), pilocarpine and timolol (col. 5, line 41 – col. 6, line 16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include said particular ophthalmic drugs in nanoparticles in the contact of Resnick with a reasonable expectation of success because the prior art suggests that a) said drugs are well-known for the purpose of treating the eye and can be used in controlled release devices.

7. Claims 6 and 16 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Resnick (US 2002/0141760), Ding (PSTT, Vol. 1, No. 8, Nov 1998), Vandamme (Progress in Retinal and Eye Research 21 (2002)15-34), Nagarsenker et al (Int. Journal of Pharmaceutics 190 (1999) 63-71) and Paul et al (Current Science, Vol. 80, No. 8, 25 April 2001) as applied to claims 1, 4-5, 7-15 and 20 above, and further in view of Raut (US 2003/0216431, filed: 8/1/2002).

Resnick/Vandamme/Nagarsenker teach the elements of claim 1, but are silent to the particular ophthalmic drugs recited in claims 6 and 16.

Raut teaches ophthalmic pharmaceutical compositions for topical administration to the eye (abstract). In a particular embodiment, Raut includes pyrimethamine (paragraph [0117]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include pyrimethamine in nanoparticles in the contact of Resnick with a reasonable expectation of success because the prior art suggests that pyrimethamine is well-known for the purpose of treating the eye and Resnick disclosed drug delivery for ocular use.

8. Claims 2-3 and 21 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Resnick (US 2002/0141760), Ding (PSTT, Vol. 1, No. 8, Nov 1998), Vandamme (Progress in Retinal and Eye Research 21 (2002)15-34), Nagarsenker et al (Int. Journal of Pharmaceutics 190 (1999) 63-71) and Paul et al (Current Science, Vol. 80, No. 8, 25 April 2001) as applied to claims 1, 4-5, 7-15 and 20 above, and further in view of Ghosh (Indian Journal of Biochemistry & Biophysics, Vol. 37, October 2000, Pg 273-282).

As taught above Resnick/Ding/Vandamme/Nagarsenker and Paul teach all the limitations of claim 1.

Regarding claim 2: Resnick teaches microsphere with an approximate diameter of .25 micrometers (approx 250nm). It would have been obvious to one of skill in the art to optimize the size of the nanoparticles dependent on the desired purpose and desired results, as taught by Ding, absent any evidence of criticality. Furthermore it would have been obvious to one of skill in the art to distribute the nanoparticles in such a manner that optical transparency is maintained.

Regarding claims 3 and 21: Claims 3 and 21 claim that the amount of nanoparticles is from about 1-5% and from 5-20%. It would have been obvious to one of skill in the art through

routine experimentation to determine the amount of nanoparticles necessary to achieve desired results, while maintaining the optical transparency of the contact lens.

Resnick does not teach the nanoparticles to have a size of less than 200nm.

Ghosh teaches the use of polymeric nanoparticles as drug particles. Said nanoparticles have a size between 10 to 100nm. Water soluble as well as insoluble drugs can be entrapped into these polymers by adjusting the hydrophilicity/hydrophobicity of the core of the nanoparticles (Abs, Pg. 273, Col. 1). Delivering drugs through polymeric nanoparticles is considered to assist in reducing the adverse reactions and side effects (Pg 273, Col. 2). These polymeric nanoparticles hold great promise of maximizing drug effectiveness while minimizing drug toxicity.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Resnick and Ghosh. One of skill in the art would have been motivated to optimize the size of the particles taught by Resnick in order to obtain nanoparticles with a size ranging between 10 and 100nm, as Ghosh teaches these to be useful drug-carriers which can entrap water soluble and insoluble drugs and reduce the possibility of adverse reactions and side effects. One of skill in the art would expect reasonable success absent evidence to the contrary and furthermore Resnick/Ding/Vandamme/Nagarsenker and Paul teach the use of nanoparticles as drug carries which encapsulate hydrophilic and hydrophobic drugs

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER BERRIOS whose telephone number is (571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Berrios/
Examiner, Art Unit 1613

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